



Guidelines for Medical Necessity Determination for Cranial Orthoses

These Guidelines for Medical Necessity Determination (Guidelines) identify the clinical information MassHealth needs to determine medical necessity for cranial orthoses in the treatment of postsurgical cranial molding, brachycephaly, and positional nonsynostotic plagiocephaly. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

These guidelines are intended for comprehensive services for the preparation, fitting, and subsequent adjustment of cranial orthoses. Providers should consult MassHealth regulations at 130 CMR 442.000 and 450.000 and Subchapter 6 of the *Orthotics Manual*, for information about coverage, limitations, service conditions, and other prior-authorization requirements. Providers serving members enrolled in a MassHealth-contracted managed care organization (MCO) should refer to the MCO's medical policies for covered services.

MassHealth reviews requests for prior authorization on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

Section I. General Information

Historically torticollis and intrauterine events have been the principal causes of plagiocephaly. However, since the 1992 American Academy of Pediatrics recommendation to place babies on their backs to sleep in order to prevent Sudden Infant Death Syndrome (SIDS), there has been an increase in diagnoses of brachycephaly and positional nonsynostotic plagiocephaly. Brachycephaly is a uniform flattening of the posterior aspect of the head. Positional nonsynostotic plagiocephaly for a baby who sleeps on his or her back is characterized by unilateral occipital flattening that is often accompanied by ipsilateral advancement of the ear and frontal region along with orbital asymmetry. Positional therapies are the primary prescription for these conditions. Cranial orthoses, head bands or helmets, are sometimes used to treat this condition when repositioning the infant fails. Cranial orthotic therapy is diminished in efficacy if instituted when head growth has stabilized, generally around age one year. Individual cases and postsurgical treatment may vary.

MassHealth considers approval for coverage of cranial orthoses for treatment of post-surgical cranial molding, brachycephaly, and positional nonsynostotic plagiocephaly causing facial, orbital, or auricular deformities that threaten the child's ability to function as described in Section II.A (Clinical Coverage), and in accordance with 130 CMR 450.204.

Section II. Clinical Guidelines

A. Clinical Coverage

MassHealth bases its determination of medical necessity for cranial orthoses on a combination of clinical data and the presence of indicators that would affect the relative risks and benefits of the product, which at minimum require a diagnosis of plagiocephaly, brachycephaly, or postcraniofacial status by a pediatric

neurologist, neurosurgeon, or craniofacial surgeon; exclusion of craniosynostosis; failure of conservative treatments; and documentation that the lesion is potentially correctable. In exceptional cases co-morbid diagnosis or delay in diagnosis may prevent completion of a trial of conservative therapy. Specifically:

1. A pediatric neurologist, neurosurgeon, or craniofacial surgeon has determined that the member does not have craniosynostosis.
2. A pediatric neurologist, neurosurgeon or craniofacial surgeon has determined that the member has brachycephaly or positional plagiocephaly that, unless corrected by a helmet or cranial banding, is likely to:
 - a. result in significant permanent deformity; or
 - b. result in visual or auditory impairment or developmental delay.
3. Clinical documentation demonstrates that flattening persists despite a minimum two-month period of positional therapy and physical therapy.
 - a. the trial of positional therapy generally began between the ages of 2 to 6 months, included extended periods of “tummy time,” posturing the infant with foam wedges, keeping objects of interest to the side opposite the posterior cranial flattening, and regular alternation of feeding sides and positions for nursing or bottle-feeding; and
 - b. the trial therapy has failed to improve the deformity and is judged to be unlikely to do so.

B. Noncoverage

Cranial orthoses are not medically necessary for brachiocephaly or plagiocephaly that is not likely to cause permanent deformity, visual or auditory impairment, or developmental delay.

Section III. Submitting Clinical Documentation

Requests for prior authorization for cranial orthoses must be accompanied by clinical documentation that supports the medical necessity for this product. In some cases photographic documentation of facial, orbital, and auricular involvement may be necessary, including frontal, lateral, and vertex images.

- A.** Documentation of medical necessity must include all of the following:
1. a written prescription by the member’s pediatric neurologist, neurosurgeon, or craniofacial surgeon for the cranial orthosis;
 2. written determination by the member’s pediatric neurologist, neurosurgeon or craniofacial surgeon that the member does not have synostotic posterior plagiocephaly;
 3. anthropometric assessment by the orthotics provider of cranial shape and measurements taken for determining cranial vault asymmetry (CVA), cranial vault asymmetry index (CVAI), and transcranial measurements of the cephalic index (CI) provided by the neurosurgeon, craniofacial surgeon, and the orthotic provider; and
 4. documentation that medical personnel have instructed caregivers (of children less than eight months old) in appropriate positional therapies that have been administered without improvement after two months;
- B.** Providers must submit all information pertinent to the diagnosis using the Automated Prior Authorization System (APAS) at www.masshealth-apas.com or by completing a MassHealth Prior Authorization Request form and attaching pertinent documentation.

Select References

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These Guidelines are based on review of the medical literature and current practice in treating deformational plagiocephaly. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of proposed treatment. Some language used in this communication may be unfamiliar to other readers; in this case, contact your health-care provider for guidance or explanation.

Policy Effective Date: July 1, 2007

Approved by:  , Medical Director